K022903

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Premarket (510k) Summary

NOV 2 7 2002

Submitter Information

Microtek Medical, Inc.
512 Lehmberg Road
Columbus, Mississippi 39702
662-327-1863
Contact person: Thomas Bonner
Date prepared: August 15, 2002

Device Name

Proprietary name: ChillBuster™ Portable Electric Blanket
Common name: Hypothermic Therapy System.
CDRH Product Regulation: Thermal Regulation System (21 CFR, 870.5900)

Establishment Registration Number: 1043582 (Microtek Medical, Inc.)

Classification: II (74 DWJ)

Statement of Substantial Equivalence

ChillBuster™ Portable Electric Blanket is equivalent to:

1. ChillBuster™ (ThermoGear K991684)
2. Life-Air 1000 (Progressive Dynamics Inc., Marshall, MI)

Description of Device

The ChillBuster™ Portable Electric Blanket System is made up of six major components:

Blanket. The main functional system element is 40"X 60" in area, featuring an oxford nylon outer layer and an inner layer of knapped acrylic blanket fabric. The unique ChillBuster™ array of special thermal wire resides between the two layers, thermal wire extensions and electrical data relative to blanket temperature exiting the blanket through a special interface and connector at one blanket corner. The latter blanket connector extends a few inches from the blanket corner, and mates with the blanket cable from the control module. The blanket can be machine washed and dried.

Control Module. Five key sub-units form this component: 1) one electric circuit board (ECB) where all control and electronics reside; 2) one user interface panel, providing information and controls; 3) Interconnect wiring to the user interface panel and to the battery; 4) a molded chassis that forms the base for the other components, along with a recessed compartment accepting two sizes of battery (see below); and 5) the blanket cable, hard wired to the ECB, and exiting the control module through the user interface panel (see cabling below);

Cabling. There are two cables associated with the system. One is the blanket cable, hard wired to the ECB, exiting the control module through the interface panel, and extending approximately six feet to a terminal connector at the blanket end of the cable. The latter connector mates with a corresponding connector that terminates a short (few inches long) pigtail cable protruding from the corner of the blanket. The other cable is an optional cigarette lighter cable, to allow system charging and/or operation using power from any vehicle cigarette lighter socket that supplies 12 volts;

Battery. The 8000 series employs a 12 volt, sealed lead acid, rechargeable battery. The control module will accept two different battery configurations, of 7 amp-hour and 4 amp-hour capacity, respectively. The purchaser specifies the desired battery capacity at the time of purchase.

AC adapter. All 8000 series systems include and standard, U2601-1 approved, AC-to-DC adapter properly matched to the voltage, current and interconnect requirements of other system components applicable to local AC line power.

Carrying Bag. ChillBuster™ systems include a custom carrying bag with several important features, including; a suitcase type carrying handle; a shoulder strap; and an internal shelf in the bag that separates the upper two thirds of the bag cavity as a blanket and cable storage compartment, leaving the lower one-third for the control module with attached battery. Removal of the blanket and cables from the carrying bag permits user access to the user interface panel on the control module.

Standards. The following standards were used in the testing of this unit:

General Medical Safety: IEC 601-1: 1998; Amd. 1: 1991; Amd. 2: 1995
UL 2601-1

EMC IEC 601-1-2

Intended Use

To reduce the effects of hypothermia encountered during the trauma of a surgical procedure or other medical crisis which could result in the onset of a hypothermic condition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2002

Microtek Medical, Inc.
c/o Mr. Thomas B. Bonner, Jr.
Vice President, Regulatory Affairs/Quality Assurance
512 Lehmberg Road
Columbus, MS 39702

Re: K022903
Trade Name: ChillBuster™ Portable Electric Blanket
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II (two)
Product Code: DWJ
Dated: August 15, 2002
Received: September 3, 2002

Dear Mr. Bonner:

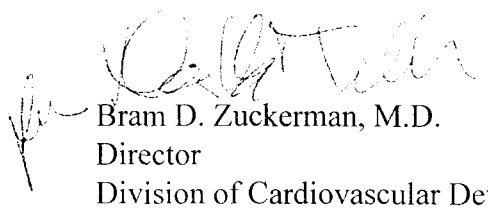
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number

Device Name: Microtek Medical, Inc. ChillBuster™ Portable Electric Blanket

Indications for Use Statement:

ChillBuster™ Portable Electric Blanket is to be used to reduce the effects of hypothermia encountered during the trauma of a surgical procedure or other medical crisis which could result in the onset of a hypothermic condition.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
And Neurological Devices

510(k) Number K022903

Prescription Use X or Over-The-Counter Use _____
(per 21CFR 801.109)